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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,418	08/03/2001	David B. Masters	45795.23.1	8113

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EXAMINER	
SULLIVAN, DANIELLE D	
ART UNIT	**PAPER NUMBER**
1617	

NOTIFICATION DATE	DELIVERY MODE
12/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IP@FREDLAW.COM

Office Action Summary	Application No.	Applicant(s)	
	09/922,418	MASTERS, DAVID B.	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/19/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/7/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response dated July 19, 2010, to the Ex Parte Quayle Action dated March 18, 2010 has been entered.

In the amendment dated March 18, 2010, claims 4,18, 24, 25, 53, 67 and 74 were amended, and claims 99-168 cancelled. No claims were newly added. Accordingly, claims 1-98 remain pending in the application.

The finality of the Office action mailed March 18, 2010 is hereby withdrawn in view of the new ground of rejection set forth below.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/7/2010 has been considered by the examiner.

Specification

The specification is objected to because the incorporation by reference filed 8/03/2001 of the following references is improper: Wakiyama et al., Hayne et al. and Langer (cited on page 43); Pierce Endogen Catalog (cited on page 49). The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the

material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-47, 50-65 and 67-96 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder et al. (US 5,514,379; May 7, 1996) in combination with Tanabe et al. (US 4,734,097; March 29, 1988).

Applicant's Invention

Applicant claims a drug delivery device comprising one or more protein materials, conductive materials, one or more pharmacologically active agents and solvents which form a cohesive body and has a solvent content of about 10% to 60% (claim 1). The protein materials are selected from collagen, albumin, thrombin, fibrinogen, fibronectin, etc. (claim 2 and 3). Claim 4 specifies the proteins are engineered with blocks of peptides that have amino acids which are. The drugs are selected from analgesics, chemoattractants and anticancer agents (Claim 7). Claim 8 specifies the compounds comprise a second, migration-vulnerable drug delivery device. The second, migration-vulnerable drug may comprise lipospheres or microsphere (claims 9 and 10). The solvents may be selected from water (Claims 5 and 6). The device may further

comprise a biocompatible polymer selected from polyethylene glycol and polyvinyl alcohol (claims 12 and 13). Claim 11 specifies the active is substantially homogeneously distributed within the device, which is treated as an inherent property of the formulation formed. The device is crosslinked with one or more crosslinking agents selected from glutarldehyde (claims 14 and 15). The conductive materials are selected from gold and aluminum (claim 16).

Applicant claims a method of making the device above comprising preparing the composition of claim 1 by forming a film, partially drying the film to form a cohesive body and compressing the cohesive body at a pressure of 100 psi to 100,000 psi to obtain a solvent content of 10-60%.

Applicant claims a electromatrix device comprising one or more polymers, conductive materials, optionally a pharmacologically active agents and solvents which form a cohesive body and has a solvent content of about 10% to 60% (claim 50). The protein materials are selected from collagen, albumin, thrombin, fibrinogen, fibronectin, etc. (claims 51 and 52). Claim 53 specifies the proteins are engineered with blocks of peptides that have amino acids which are. The drugs are selected from analgesics, chemoattractants, agents (Claim 56). Claim 57 specifies the compounds comprise a second, migration-vulnerable drug delivery device. The second, migration-vulnerable drug may comprise lipospheres or microsphere (claims 58 and 59). The proteins may be selected from fibrinogen and thrombin. The solvents may be selected from water (Claims 54 and 55). Claim 60 specifies the active is substantially homogeneously distributed within the device, which is treated as an inherent property of the formulation

formed. The device may further comprise a biocompatible polymer selected from polyethylene glycol and polyvinyl alcohol (claims 61 and 62). The device is crosslinked with one or more crosslinking agents selected from glutarldehyde (claims 63 and 64). The conductive materials are selected from gold and aluminum (claim 65).

Applicant claims a method of making the device above comprising preparing the composition of claim 50 by forming a film, partially drying the film to form a cohesive body and compressing the cohesive body at a pressure of 100 psi to 100,000 psi to obtain a solvent content of 10-60%.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Weissleder et al. teaches biocompatible, biodegradable hydrogels prepared from a backbone boned to a cross-linking agent where suitable backbones include albumin globulins, collagen, fibrinogen, fibrin and thrombin, where therapeutic drugs are therein incorporated (abstract; column 6, line 51-60; limitation of claims 2, 3, 51 and 52). Polylysines, amino acid proteins and those that are fractionated into peptide fragments are also taught with polyethylene glycol (column 7, lines 13-20; limitation of claims 4, 12, 13, 53, 61 and 62). The use of hydrogels and microspheres, such as fibrinogen microspheres and polylactic sphere are taught (column 3, lines 8-16, limitation of claims 9, 10, 58 and 59). The use of glutaraldehyde as a crosslinker for albumin gels (column 2, lines 33-37; limitation of claims 14, 15, 63 and 64). Protein-based backbones for protein based gels contain 20-50% protein in the initial solution (column 6, lines 40-44).

The gels are water-swellable which aids them in MR imaging and CT scans (column 3, lines 28-45, limitation of claims 5, 6, 54 and 55 is the use of water). The hydrogels may be used of coating medical devices such as stents for implantation (column 10, lines 35-46, limitation of claims 8 and 57). The backbone is crosslinked to produce the hydrogel (column 4, lines 35-37, limitation of 11 and 60). Polyethylene glycol may be used as a back (column 4, lines 31-34; limitation of claims 12, 13, 61 and 62). Therapeutic drugs include analgesics, chemotherapy agents, hormones and antibiotics (column 9, lines 24-43, limitation of claims 7 and 56). Radiopaque metals selected from gold and aluminum may be used for diagnostic purposes (column 8, lines 33-48, limitation of claims 16 and 65).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Weissleder et al. do not teach specific solvent content of about 20-80% prior to compression and 10-60% after compression or disclose a method of making the formulation by forming a film, partially drying the film to form a cohesive body and compressing the cohesive body at a pressure of 100 psi to 100,000 psi to obtain a solvent content of 10-60%. It is for this reason that Tanabe et al. is joined.

Tanabe et al. teach a method of making a molded hydrogel comprising polyvinyl alcohol, for medical use which can be freeze molded to a percent dehydration of not less than 5% wt, preferably not less than 10% and a possible water content of 45-95% (abstract; column 7, lines 14-20). The solution of ingredients is compressed up to a tensile strength of 10 kg/cm2 (142 psi) (column 20, lines 42-45). The step of

dehydrating aids in strengthening the gel and imparting a non-sticky water resistant product with improved strength and elasticity(column 7, lines 21-25).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

Weissleder et al. and Tanabe et al. both encompass hydrogel compositions. Therefore it would have been *prima facie* obvious to formulate a hydrogel composition with a water content of 45-65%, at the time of the instant invention, with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to apply the method steps of partially drying and compressing the composition in order to formulate a molded hydrogel with improved strength and elasticity.

Claims 1, 17-19, 48-50, 66-68, 97and 98 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over in Weissleder et al. (US 5,514,379; May 7, 1996) in combination with Tanabe et al. (US 4,734,097; March 29, 1988), as applied to claims 1-47, 50-65 and 67-96 above, and in further view of Kucharczyk et al. (US 6,026,316; February 15, 2000).

Applicant's Invention

Applicant claims a drug delivery device comprising one or more protein materials, conductive materials, one or more pharmacologically active agents and solvents which

form a cohesive body and has a solvent content of about 10% to 60% (claim 1). The conductive material is preferably an alloy selected from stainless steel (claim 17).

Applicant claims a method of making the device above comprising preparing the composition of claim 1 by forming a film, partially drying the film to form a cohesive body and compressing the cohesive body at a pressure of 100 psi to 100,000 psi to obtain a solvent content of 10-60%.

Applicant claims a electromatrix device comprising one or more polymers, conductive materials, optionally a pharmacologically active agents and solvents which form a cohesive body and has a solvent content of about 10% to 60% (claim 50). The conductive material is preferably an alloy selected from stainless steel (claim 66).

Applicant claims a method of making the device above comprising preparing the composition of claim 1 by forming a film, partially drying the film to form a cohesive body and compressing the cohesive body at a pressure of 100 psi to 100,000 psi to obtain a solvent content of 10-60%.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

The teachings of Weissleder et al. in combination with Tanabe et al. are disclosed in the above 103 rejection.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Weissleder et al. and Tanabe et al. do not teach a the conductive material is an alloy of a metal selected from stainless steel. It is for this reason that Kucharczyk et al. is joined.

Kucharczyk et al. teach a method of drug delivery using MR imaging to track the drug (abstract). To improve MR visualization of implanted devices conductive materials are chosen from nitinol and stainless steel alloy (column 6, lines 11-17). To make the MR visible a catheter comprising a biocompatible and MR compatible material selected from hydrogels may be used (column 4, lines 16-35).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

Weissleder et al., Tanabe et al. and Kucharczyk et al. are all drawn to formulations which comprise hydrogels. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Weissleder et al., Tanabe et al. and Kucharczyk et al. to include an alloy of stainless steel in order to improve MR visualization with a reasonable expectation of success. Hence, selecting label on the drug which is an alloy would have been obvious to one of ordinary skill.

Conclusion

In view of the new rejections, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE SULLIVAN whose telephone number is (571)270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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